

Practitioner's Docket No. MPI01-019P1RNM

PATENT

In re application of:	Olandt, Peter J. et al.		
Application No.:	10/074,527	Group No.:	1652
Filed:	February 12, 2002	Examiner:	Rao, Manjunath N.
For:	33945, A HUMAN GLYCOSYLTRANSFERASE AND USES THEREFOR		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We, Peter J. Olandt, Rachel E. Meyers, and Katherine M. Galvin hereby declare and state:

1. In the United States, the conception of the sequence of the human 33945 molecules of the invention and the identification of the 33945 polypeptide as a glycosyltransferase occurred prior to December 15, 2000 and the reduction to practice comprising obtaining the final sequence known as SEQ ID NO:1 in the above-identified application was performed with due diligence until December 18, 2000, the date of the actual reduction to practice.
2. Evidence of conception prior to December 15, 2000 is provided in Exhibits A1-A3, which are copies of electronic printouts of a map of clones contributing to the 33945 nucleotide sequence and analyses of early 33945 sequences.

Exhibit A1 is a copy of page 1 of a Sequencher™ map identifying the clones contributing to the 33945 nucleotide sequence, the clone sizes and the positions of the clones relative to the 33945 sequence known at that stage of the invention process. Exhibit A2 is a copy of a BLAST analysis of a translation of that nucleotide sequence. The map was compiled and the analysis was

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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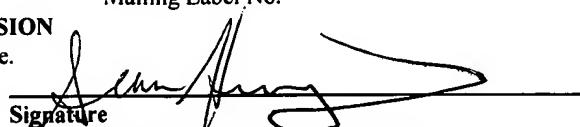
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performed prior to December 15, 2000. By that time, the sequence was extensive, spanning 2109 nucleotides, and the BLAST revealed similarity of the 33945 polypeptide to glycosyltransferases. Exhibit A3 is a copy of a series of analyses performed on the polypeptide encoded by that 33945 nucleotide sequence. Page 1 of this printout bears the nearly complete polypeptide sequence known at the time, showing that it has the full length of 581 amino acids, but a few uncertain residues; page 3 bears the results of a Pfam analysis which matched a portion of the 33945 sequence with the Pfam Glycosyl transferase domain consensus sequence; pages 4 and 5 bear the results of an analysis which matched portions of the 33945 polypeptide sequence with glycosyltransferase domain consensus sequences from the ProDom database. The combined result of the analyses was the determination that the 33945 molecules of the invention represent a glycosyltransferase.

The original printouts in Exhibits A1-A3 bear the automatically embedded dates on which the analyses were performed. In accordance with accepted practice, the dates on the copies of the electronic printouts have been masked (M.P.E.P. § 715.07).

3. Evidence of the exercise of due diligence in the process of reducing to practice the 33945 molecules of the invention is provided in Exhibits B1-B5. In accordance with M.P.E.P. § 715.07, the actual dates of the acts portrayed in Exhibits B1-B5 have been provided to establish diligence. In accordance with M.P.E.P. § 715.07(a), the acts performed just prior to the effective date of December 15, 2000 until the December 18, 2000 date of the actual reduction to practice are included in Exhibits B1-B5.

Exhibit B1 is a copy of page 1 of an updated Sequencher™ map compiling the clones contributing to the 33945 nucleotide sequence as understood by November 27, 2000. One can see from this Exhibit, additional 5' clones "fbhX33945phg01b1.abi" and "fbhX33945phh01b1.abi" which were not present on Exhibit A1. In addition, Exhibit B1 has a note written by inventor Peter Olandt, describing a 2 base pair problem needing to be solved. In order to solve this problem, additional clones were prepared to cover the region in question. This clone preparation process yielded four additional 5' clones, "fbhX33945peb04h1," "fbhX33945pee03g1," "fbhX33945pf04h1" and "fbhX33945pfg03g1."

Clone "fbhX33945pee03g1" is used herein as an example of the timecourse and types of analyses performed on these clones to show due diligence. Exhibit B2 provides a summary of the facts related to clone "fbhX33945pee03g1", together with its nucleotide sequence. At the top of Exhibit B2, one can see that this clone was submitted for sequencing on December 12, 2000. As seen in the middle of the Exhibit, "fbhX33945pee03g1" came out of sequencing on December 14, 2000 and was submitted for analyses. The first analysis was performed on December 14, 2000, and subsequent analyses were performed on December 15 and 16, 2000.

Exhibit B3 shows that on Monday, December 18, 2000, the four new clones were assembled into a new Sequencher™ clone map. The problem of base pair selection was solved and the complete 33945 nucleic acid sequence ("Fbh33945FL"), known in the application as SEQ ID NO:1 was finalized and submitted to the Millennium database on Monday, December 18, 2000, as shown on Exhibit B4. Exhibit B5, also performed on December 18, 2000, shows that analyses performed on the polypeptide encoded by the complete nucleotide sequence supported the earlier conclusion of 33945 as a glycosyltransferase drawn from the evidence of prior conception provided in Exhibits A2 and A3.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Peter J. Olandt

Date

Rachel E. Meyers

Date

Rachel E. Meyers

Date

Katherine M. Galvin

Date